REMARKS

This Reply is set forth under appropriate subheadings for the convenience of the Examiner.

Amendment to Claim 4 and New Claims 49 and 50

Claim 4 has been amended and new Claims 49 and 50 added to more clearly define that which Applicants regard as the invention. Support for the amendments to Claim 4 can be found in the specification and claims as originally filed. For example, page 20, lines 28-32 and original Claim 5 describes detecting a C to G change at nucleotide number 205 in the EPM2B gene sequence comprising SEQ ID NO: 1, thereby providing support for the amendment to Claim 4. Page 20, line 23 through page 21, line 31, Table 1, and original Claims 6-25 describes methods for detecting specific mutations in the EPM2B gene comprising SEQ ID NO: 1, thereby providing support for new Claim 49. Page 23, lines 4-14 describe amplification of nucleic acids in a test sample using suitable PCR primer sequences prior to analysis, thereby providing support for new Claim 50.

No new matter has been added in the amendment to Claim 4 or in new Claims 49 and 50. Entry of the amendment to Claim 4 and new Claims 49 and 50 is requested.

Objection to Claim 48

The Examiner objected to Claim 48 as being of improper dependent form. Claim 48 has been canceled, thus obviating this objection.

Rejection of Claims 4, 41 and 45 Under 35 U.S.C. § 112, First Paragraph

Claims 4, 41 and 45 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not disclosed in the specification in such as way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner states that "[t]he claims broadly encompass any mutation which is a missense, nonsense, insertion, deletion, point mutation or frameshift which 'affects a

portion of the EPM2B gene encoding a RING finger domain or an NHL motif of SEQ ID NO: 1.'"

Claims 41 and 45 have been canceled, thereby obviating the rejection as to these claims.

Claim 4, as amended, is directed to a method of detecting the presence of, or predisposition to, Lafora's disease in a human, wherein the Lafora's disease is associated with a mutation in the EPM2B gene~~,~~ comprising detecting a C to G change at nucleotide number 205 in the EPM2B gene sequence comprising SEQ ID NO:1. The specification provides descriptions of this mutation that at, for example, page 20, lines 28-32, Table 1 and in original Claim 5.

Thus, Claim 4 as amended, satisfies the written description requirements of 35 U.S.C. §112, first paragraph.

Rejection of Claims 4-5, 26, 41 and 43-46 Under 35 U.S.C. § 112, first paragraph

Claims 4-5, 26, 31, 41 and 43-46 were rejected under 35 U.S.C. § 112, first paragraph because the specification, while being enabling for a method of detecting Lafora's disease in a human subject comprising obtaining a sample from the human subject and detecting a G at position 205 of SEQ ID NO: 1 wherein the presence of a G at position 205 of SEQ ID NO: 1 is indicative of Lafora's disease, does not reasonably provide enablement for a method of detecting Lafora's disease in a mammal, including a human, by detecting a missense, nonsense or frameshift which results in a deleterious effect on the encoded protein product including a nucleotide change at position 205 of SEQ ID NO: 1. The Examiner stated that the specification does not enable any person skilled in the art to which it pertains, or with which it is nearly connected, to make and use the invention commensurate with the scope of the claims. The Examiner stated that Applicants' claims were evaluated for enablement based on the Wands factors as set forth in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

Claims 5, 26, 41 and 45-46 have been canceled, thereby obviating the rejection as to these claims.

Claim 4, as amended is directed to a method of detecting the presence of, or predisposition to, Lafora's disease in a human, wherein the Lafora's disease is associated with a mutation in the EPM2B gene~~,~~ comprising detecting a C to G change at nucleotide number 205 in

the EPM2B gene sequence comprising SEQ ID NO:1. Applicants believe that this amendment obviates the rejection as to Claim 4.

Claim 43 is directed to a method of detecting the presence or absence of a mutation in the nucleic acid sequence of the EPM2B gene (i.e., SEQ ID NO: 1) in a human. The Examiner stated that the word "mutation" in Claim 43 "is presumed not to [be] the same as a natural variation." However, the word "mutation" is defined in the specification at page 20, lines 9-13 as "any change or difference in the nucleic acid or protein sequence of EPM2B as compared to the wild type sequence. Mutations include, but are not limited to, nonsense mutations, missense mutations, frameshift mutations, rearrangement mutations, insertion mutations and deletion mutations." This definition clearly includes natural variations in the EPM2B gene. Moreover, the specification provides ample guidance to one of skill in the art to detect mutations in the EPM2B gene. For example, page 22, lines 1-19, describes a number of methods for detecting mutations. Thus, Claim 43 meets the enablement requirement of 35 U.S.C. §112, first paragraph.

Thus, Claims 4 and 43 satisfy the requirements of 35 U.S.C. § 112, first paragraph, and reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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